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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/009,030

08/19/2002

Michael Arand

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20311

7590

10/01/2004

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,030

Applicant(s)

ARAND ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 1, 2, 4-6, 8 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in that the deleted portion of the claims is not unambiguously crossed out. Apparently "or protein...hydrolase activity" was intended to be deleted but this cross out was done free hand with a pen and some of the words are not definitively crossed out.

Claims 2, 4-6 and 8 are incorrect in the recitation of "SEQ ID No:" numerous times, which should be "SEQ ID NO:".

Claim 4 is incorrect in the recitation of "epxoide", which should apparently be "epoxide".

Claim 6 is incorrect in the recitation of "SEQ ID N.:", which should be "SEQ ID NO:". The claim is also confusing in that it is apparently of the same scope as claim 5.

Claim 8 is indefinite in the recitation of "preferably" on line 12. It is not known whether the instant recitation is meant to be a limitation on the claim or simply illustrative. This rejection is repeated from the previous action. The claim is also incorrect in the recitation of "hydroloase" on line 17, which should be "hydrolase".

Claims 12 and 14 are indefinite in the recitation of "optionally" on lines 19 and 5, respectively. It is not known whether the instant recitation is meant to be a limitation on the claim or simply illustrative. This rejection is repeated from the previous action. Applicants state that this word has been deleted but it has not.

Claim 12 is indefinite in the recitation of "in which R¹, R², R³ and R⁴ represent any group characteristic of pharmaceutical and plant-protection compounds". It is not known to what the instant claim is intended to be lim-

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ited as these groups that are characteristic of pharmaceutical and plant-protection compounds are not defined. Applicants state that "it is deemed that it is adequately illustrated in the specification and the definition thereof as being any group characteristic of pharmaceutical and plant protection compounds is well known to those skilled in the art". There is no place in the specification is pointed to as illustrating this and no prior art showing that this "is well known to those skilled in the art".

Claim 12 is also confusing in the recitation of "of specific optical forms corresponding to the said epoxides or vicinal diols" on 5-6. It is not known what was intended by this recitation and furthermore it is not seen where this recitation has enablement in the specification. This rejection is repeated from the previous action. Applicants did not address this rejection in the instant amendment.

Claim 12 is also confusing in the recitation of "with epoxide hydro-lase" on line 16, which should apparently be "with epoxide hydrolase activity" as in the original claim.

Claim 12 is also confusing and apparently incorrect in the recitation of "aid" on line 19, which should apparently be "said".

Claim 13 is confusing and apparently incorrect in the recitation of "hydrloase" on line 1, which should apparently be "hydrolase".

Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims in the alternative only. The instant claim depend from both claims 5 and 9. See MPEP § 608.01(n). This rejection is repeated from the previous action. Applicants did not address this objection in the instant amendment.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-10 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

As stated previously, the instant specification teaches and enables an epoxide hydrolase from *Aspergillus niger* that has the sequence SEQ ID NO:2 and is encoded by SEQ ID NO:1. Claim 1, upon which the other claims ultimately depend, is drawn to epoxide hydrolases from "cells of fungi" that may be "obtained in pure form by extraction from cells of fungi, or by culture of host cells transformed by culture of host cells transformed by a nucleotide sequence coding for the aforementioned fungal protein". Applicant have deleted the phrase "derived by substitution, suppression or addition of one or more amino acids of the aforementioned protein" but have not addressed the rest of the enablement rejection. It is noted that claim 8 still contains the phrase "derived from the sequence SEQ ID No:1 [sic, NO:1], by substitution, suppression or addition of one or more nucleotides", even though it ultimately depends from claim 1. The sequence contains the additional limitation of "having a homology of at least about 45% with the sequence of SEQ ID

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No:1 [sic, NO:1]. It is pointed out that sequence with this low homology read on a large number of nucleotide sequences.

As discussed in the previous rejection, claim 4 is drawn to obtaining SEQ ID NO:2 from *Aspergillus turingensis*, when the specification teaches that SEQ ID NO:2 was obtained from *Aspergillus niger*. It has not been argued that SEQ ID NO:2 can be obtained from *Aspergillus turingensis*.

In arguing the instant rejection applicants state that "[i]t is believed that the amended claims properly define the invention since the expression objected to by the Examiner has been deleted from claim 1". They do not further argue the rejection.

Claims 1-10 and 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is added because applicants have changed "essentially pure" to "pure" in claims 1, 3-5 and 14. There is not enablement in the specification for purifying the epoxide hydrolase to complete purity, as the term is recognized in the prior art. Applicants do have enablement for purifying the epoxide hydrolase to "electrophoretic homogeneity" on page 14, line 3. Complete purity requires much more than simply running a natural or SDS gel and obtaining a single band.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the

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differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4, 12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Nellaiah, et al. (AD) or Morisseau, et al. (U) in view of the general knowledge in the prior art. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants argue that the enzyme taught by Morisseau, et al. is a soluble enzyme and that the process "only led to a very crude cell extract containing this indefinite native activity". It is maintained that the instant reference teaches an epoxide hydrolase from *Aspergillus niger* that was purified by centrifugation of the extract and passing through a Q-Sepharose column. Until applicants replace "pure" with an enabled term, this rejection is maintained.

Applicants discuss the purification in the paragraph spanning pages 11-12 of their reply, stating that it would be impossible to predict an efficient method of purification not knowing the characteristics of the enzyme and among other things stating that "Applicants worked very diligently for several months, if not a year, to set up the efficient purification conditions finally described in reference V". This is not deemed probative evidence. At the very least applicants should submit a declaration by one with knowledge in the field of enzyme purification that one of ordinary skill in the art could not purify the enzyme to the purity discussed in the specification.

The rejection over Nellaiah, et al. was not addressed in applicants' reply and is therefore repeated.

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Claims 1, 12 and 15 are rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Chartrain, et al. (B) in view of the general knowledge in the prior art. Applicants have now limited the instant claims to a "pure" epoxide hydrolase, but this term is not considered enabled by the specification (see 35 USC § 112 first paragraph rejection *supra*). It is maintained that one of ordinary skill in the art could purify the enzyme activity taught by the instant reference, absent convincing proof to the contrary. Applicants should consider submitting a declaration by one with knowledge in the field of enzyme purification that one of ordinary skill in the art could not purify the enzyme to the purity discussed in the specification.

The previous rejection over Morisseau, et al. (V) is hereby dropped. Although applicants did not address the rejection in their remarks, the examiner ascertained that the reference was published in July 1999, after the priority date of the instant application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

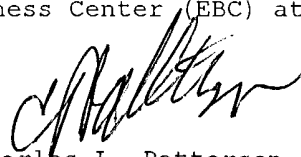
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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 29, 2004